



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 19, 2015

Neurosoft Ltd.
c/o Enrico Bisson
Studio d'Ingegneria Enrico Bisson
Via Marzia n. 9
Abano Terme, Padova 35031
Italy

Re: K133995

Trade/Device Name: Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3,
Neuron-Spectrum-4 and Neuron-Spectrum- 4/P with Neuron-
Spectrum.NET software

Regulation Number: 21 CFR 882.1400

Regulation Name: Electroencephalograph

Regulatory Class: Class II

Product Code: OLT, OLV, GWQ

Dated: May 11, 2015

Received: May 20, 2015

Dear Mr. Bisson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Felipe Aguel -S
for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (*if known*)

K133995

Device Name

Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P digital systems with Neuron-Spectrum.NET

Indications for Use (*Describe*)

The digital systems Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P with Neuron-Spectrum.NET software are intended for use as digital neurophysiological systems intended for recording, processing and display biopotential signals such as Electroencephalography (EEG) and long-latency Evoked Potential (EP). Polysomnography (PSG) derives from Electroencephalography (EEG) by the means of a dedicated software module and dedicated electrodes.

The devices are portable and can register up to 8 (Neuron-Spectrum-1), 16 (Neuron-Spectrum-2), 19 (Neuron-Spectrum-3), 21 (Neuron-Spectrum-4, Neuron-Spectrum-4/P) EEG channels, 1 (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3 and Neuron-Spectrum-4) or up to 4 polygraphic channels (Neuron-Spectrum-4/P: ECG, EOG), 1 breath channel and 2 direct current channels (Neuron-Spectrum-4/P).

Neuron-Spectrum.NET includes the Evoked potentials averaging function and Quantitative electroencephalography (qEEG) , including specific parameters such as Rhythmicity, FFT power ratio and amplitude metrics

The devices do not provide alarms, do not provide automated event marking and do not provide to the user any diagnostic conclusion about the patient's condition. They are intended for use in the patient care institutions, diagnostics centers, neurosurgical hospitals experimental laboratories and sleep laboratories. The patient group includes all ages and sexes.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 05

510K Summary

APPLICANT

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Date Summary Prepared: June, 11 2015

DEVICE IDENTIFICATION

Generic Device Name: Bio-Potential Signal Acquisition System

Trade/Proprietary Name: Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P with Neuron-Spectrum.NET software

Classification Name: 21 CFR 882.1400 Electroencephalograph
Class.II
Product Code: OLT, OLV, GWQ.

Panel: Neurology

LEGALLY MARKETED DEVICES (PREDICATE DEVICES)

Predicate Devices	510(K) Holder/Applicant	510(k) No.	Reason.
CERVELLO™ BIO-POTENTIAL SIGNAL ACQUISITION SYSTEM	Blackrock Neuromed, LLC	K122196	Overall functions
Persyst 12 Eeg Review And Analysis Software	Persyst Development Corp	K132306	Software functions
Alice 5 System	Respironics , INC.	K040595	Polysomnographyfunction
Focus EMG Device	TELEEMG, LLC	K102610	Auditory stimulator
Neurofax m EEG-9100	Nihon Kohden Corporation	K011204	Photic Stimulator

DEVICE DESCRIPTION

The digital systems Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P with Neuron-Spectrum.NET software are intended for use as digital neurophysiological systems intended for recording, processing and display biopotential signals such as Electroencephalography (EEG) and long-latency Evoked Potential (EP). Polysomnography (PSG) derives from Electroencephalography (EEG) by the means of a dedicated software module and dedicated electrodes.

The devices are portable and can register up to 8 (Neuron-Spectrum-1), 16 (Neuron-Spectrum-2), 19 (Neuron-Spectrum-3), 21 (Neuron-Spectrum-4, Neuron-Spectrum-4/P) EEG channels, 1 (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3 and Neuron-Spectrum-4) or up to 4 polygraphic channels (Neuron-Spectrum-4/P: ECG, EOG), 1 breath channel and 2 direct current channels (Neuron-Spectrum-4/P).

Neuron-Spectrum.NET includes the Evoked potentials averaging function and Quantitative electroencephalography (qEEG) , including specific parameters such as Rhythmicity, FFT power ratio and amplitude metrics.

The devices do not provide alarms, do not provide automated event marking and do not provide to the user any diagnostic conclusion about the patient's condition. They are intended for use in the patient care institutions, diagnostics centers, neurosurgical hospitals experimental laboratories and sleep laboratories. The patient group includes all ages and sexes.

The operation of the device in the video EEG monitoring mode is possible for not more than 30 days.

The general properties, when carrying out EEG or EP study using EEG channels:

- 8 (Neuron-Spectrum-1), 16 (Neuron-Spectrum-2), 19 (Neuron-Spectrum-3), 21 (Neuron-Spectrum-4, Neuron-Spectrum-4/P) channels EEG/EP recording in any unshielded room;
- up to 2 direct current channels recording (Neuron-Spectrum-4/P);
- photic, auditory stimulation and stimulation carrying out with the use of reversal checkerboard pattern (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P);
- synchronous long-term recording of EEG and video from one, two or three video cameras and recording of audio information from one or two microphones performed using Neuron-Spectrum-Video.NET (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P);
- long-latency EP recording using EEG channels: flash and reversal pattern visual, auditory and cognitive (P300, MMN, CNV) performed using Neuron-Spectrum-LEP.NET software (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P);
- amplitude, spectral, exam report generation, export and import of files in the standard European data format (EDF) (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P);
- review, store and print of the recorded traces, results of their analysis and exam reports (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P);
- respiratory analysis, heart rate analysis, (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P);
- snoring analysis, limb movement analysis during sleep (Neuron-Spectrum- 4/P);
- body position analysis (Neuron-Spectrum- 4/P), eye movement trends (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P);
- EMG amplitude trends and CPAP pressure trends (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P).

A patient stimulation can be performed with the use of stimulators built in the device.

The main condition for using the digital EEG systems is the good professional skills of the medical staff.

Digital EEG system mode of operation is based on the acquisition and input of brain biopotentials and

other physiological signals into PC for the analysis of brain electrical activity taking into account the influence of the other physiological signals.

Digital EEG system operates under control of PC (IBM PC type) with the mouse, keyboard, laser or ink jet printer and installed licensed Windows XP/Vista/7/8 operational system. Signal processing, displaying and presentation in different modes after mathematical analysis, storing of the EEG traces on the hard disc, exam report generation and their printing is done with the use of PC.

The typical schematics of the equipment location when connecting to the desktop PC is given on the Fig. 1

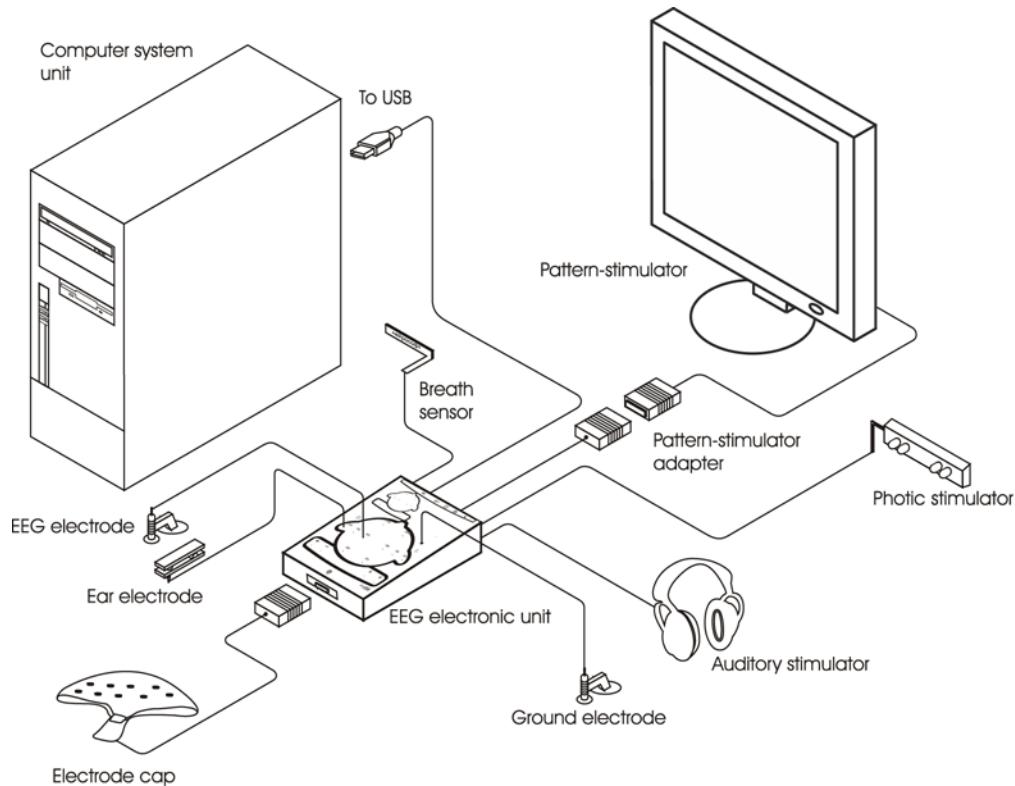


Fig.1 Connection scheme.

All the operation of displaying, analyzing and reporting the biopotentials and other physiological signals are demanded to the software Neuron-Spectrum.NET that runs in the PC connected to Neuron-Spectrum device.

Exactly the main operations provided by Neuron-Spectrum.NET software are:

- EEG Acquisition
- EEG Review, Editing, Storing, Exporting.
- EEG Analysis
- Creation of Exam Reports
- Program Setup

There are then additional software packages:

Optional Software	
Neuron-Spectrum-PSG	This software allows performing comprehensive polysomnography studies (manual sleep stage analysis, analysis of sleep-disordered breathing) on digital EEG system Neuron-Spectrum-4/P. All the rest models of Neuron-Spectrum series provide only manual sleep stage analysis.
Neuron-Spectrum-Video	This software allows performing the long-term synchronous EEG and video recording from one or two video cameras controlled from the computer and audio information from one or two microphones. There are wide possibilities to review, edit and store the recorded data
Neuron-Spectrum-LEP	This software allows recording long-latency auditory, visual (on flash and pattern), somatosensory and cognitive (P300, MMN, CNV) EP using EEG channels (up to 21 ones) with brain mapping with the use both built-in stimulators.

INTENDED USE /INDICATIONS FOR USE

The digital systems Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P with Neuron-Spectrum.NET software are intended for use as digital neurophysiological systems intended for recording, processing and display biopotential signals such as Electroencephalography (EEG) and long-latency Evoked Potential (EP). Polysomnography (PSG) derives from Electroencephalography (EEG) by the means of a dedicated software module and dedicated electrodes.

The devices are portable and can register up to 8 (Neuron-Spectrum-1), 16 (Neuron-Spectrum-2), 19 (Neuron-Spectrum-3), 21 (Neuron-Spectrum-4, Neuron-Spectrum-4/P) EEG channels, 1 (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3 and Neuron-Spectrum-4) or up to 4 polygraphic channels (Neuron-Spectrum-4/P: ECG, EOG), 1 breath channel and 2 direct current channels (Neuron-Spectrum-4/P).

Neuron-Spectrum.NET includes the Evoked potentials averaging function and Quantitative electroencephalography (qEEG) , including specific parameters such as Rhythmicity, FFT power ratio and amplitude metrics.

The devices do not provide alarms, do not provide automated event marking and do not provide to the user any diagnostic conclusion about the patient's condition. They are intended for use in the patient care institutions, diagnostics centers, neurosurgical hospitals experimental laboratories and sleep laboratories.The patient group includes all ages and sexes.

The Neuron-Spectrum devices with Neuron-Spectrum.NET software bring together similar functions from a previously cleared for market device; namely CERVELLO™ BIO-POTENTIAL SIGNAL ACQUISITION SYSTEM (K122196), Persyst 12 Eeg Review And Analysis Software(K132306), Alice 5 System (K040595) , Focus EMG Device (K102610) and Neurofax m EEG-9100 (K011204)

SUBSTANTIAL EQUIVALENCE

The **Neuron-Spectrum devices with Neuron-Spectrum.NET software** are of comparable type and are substantially equivalent to the following predicate device:

Predicate Device	510(K) Holder	510(k) No.	Date Cleared
CERVELLO™ BIO-POTENTIAL SIGNAL ACQUISITION SYSTEM	Blackrock Neuromed, LLC	K122196	05/02/2013
Persyst 12 Eeg Review And Analysis Software	Persyst Development Corp	K132306	11/21/2013
Alice 5 System	Respironics , INC.	K040595	03/18/2004
Focus EMG Device	TELEEMG, LLC	K102610	03/04/2011
Neurofax m EEG-9100	Nihon Kohden Corporation	K011204	05/08/2001

The substantial equivalence determination is discussed in Section 12 Substantial Equivalence Discussion.

Predicate devices indications for use

K122196:The Blackrock NeuroMedCervello™ Bio-Potential Signal Acquisition System contains the following configurations:

Ambulatory: Up to 64 channels with one Cervello hardware device (Amplifier) using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG. The Cervello Ambulatory System does not make any judgement of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

Basic: Up to 64 channels with one Cervello hardware device (Amplifier) and up to 128 channels by cascading 2 Cervello devices using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG. The Cervello Basic System does not make any judgement of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

Elite: Up to 128 with one Neuroport Bio-Potential Recording Systems and up to 256 by cascading two Neuroport systems using the Central and/or Cervello software. The system supports recording, processing and display of bio-potential signals from user-supplied electrodes. Bio-potential signals include: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), Electrocardiography (ECG), Electrooculography (EOG) and Evoked Potential (EP). Intended users include

Physicians, technicians, clinicians or other medical professionals that are trained in bio-potential and/or EEG recording. The Cervello Elite System does not make any judgement of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

K132306: The Persyst Development Corp. Persyst 12 Eeg Review And Analysis Software contains the following indication for use:

1-Persyst 12 EEG Review and Analysis Software is intended for the review, monitoring and analysis of EEG recordings made by electroencephalogram (EEG) devices using scalp electrodes and to aid neurologists in the assessment of EEG. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.

2-The Seizure Detection component of Persyst 12 is intended to mark previously acquired sections of adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic seizures, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with a full scalp montage according to the standard 10/20 system.

3-The Spike Detection component of Persyst 12 is intended to mark previously acquired sections of the patient's EEG recordings that may correspond to spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. The Spike Detection component is intended to be used in patients at least one month old. Persyst 12 Spike Detection performance has not been assessed for intracranial recordings.

4-Persyst 12 includes the calculation and display of a set of quantitative measures intended to monitor and analyze the EEG waveform. These include FFT, Rhythmicity, Peak Envelope, Artifact Intensity, Amplitude, Relative Symmetry and Suppression Ratio. Automatic event marking is not applicable to the quantitative measures. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG waveforms.

5-The aEEG functionality included in Persyst 12 is intended to monitor the state of the brain. The automated event marking function of Persyst 12 is not applicable to aEEG.

6- Persyst 12 provides notifications for seizure detection, quantitative EEG and aEEG that can be used when processing a record during acquisition. These include an on screen display and the optional sending of an email message. Delays of up to several minutes can occur between the beginning of a seizure and when the Persyst 12 notifications will be shown to a user. Persyst 12 notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.

7-Persyst AR (Artifact Reduction) is intended to reduce EMG, eye movement, and electrode artifacts in a standard 10-20 EEG recording. AR does not remove the entire artifact signal, and is not effective for other types of artifacts. AR may modify portions of waveforms representing cerebral activity. Waveforms must still be read by a qualified medical practitioner trained in recognizing artifact, and any interpretation or diagnosis must be made with reference to the original waveforms.

8-This device does not provide any diagnostic conclusion about the patient's condition to the user.

K040595 :TheRespironics , INC. Alice 5 Systemcontains the following indication for use:

The Alice 5 System is a Polysomnography System that is intended to record, display and print physiological information to clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centres or clinics, or other test environments where adults

or infant patients require the documentation of various sleep or other physiological disorders.

This device does not provide alarms and, is not intended for use as an automated apnoea monitor.

K102610 :TELEEMG, LLC USA FOCUS EMG DEVICE contains the following indication for use:

The Focus is intended for use by a healthcare provider to perform nerve conduction and EMG studies as an aid in the evaluation of patients with diseases of muscle and nerves. The machine can also use electrical stimulus or sound stimulus for evoked potentials (EP) studies.

K011204: Nihon Kohden Corporation Neurofax m EEG-9100 Operator's manual contains the following information:

The EEG-9100A/G/J/K Electroencephalograph is designed for both clinical and research use. This electroencephalograph realizes the conventional EEG's functions in a GUI (graphical user interface) environment. It provides powerful data filing and easy operation. The EEG waveforms and patient information are saved in a large capacity media (hard disk, MO disk or CD-R/CD-RW disk).

12.3Table . Hardware Comparison with the Predicate Device Cervello™ Bio-Potential Signal Acquisition System

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM-1,2,3,4,4/P NEUROSOFT Ltd (Submitted Product)	LEGALLY MARKETED PREDICATE DEVICES OF Cervello™ Bio-Potential Signal Acquisition System Blackrock NeuroMedLLC
'K" numbers	K133995	K122196
Proprietary / Trade Name	Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum-4/P with Neuron-Spectrum.NET Software	Cervello™ Bio-Potential Signal Acquisition System
CFR Section	882.1400	882.1400
Pro-code	OLT, OLV, GWQ	GWQ, OLV, GWL, GWK
Classification name	Electroencephalograph	Electroencephalograph
Indications For Use	<p>The digital systems Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum-4/P with Neuron-Spectrum.NET software are intended for use as digital neurophysiological systems intended for recording, processing and display biopotential signals such as Electroencephalography (EEG) and long-latency Evoked Potential (EP). Polysomnography (PSG) derives from Electroencephalography (EEG) by the means of a dedicated software module and dedicated electrodes. The devices are portable and can register up to 8 (Neuron-Spectrum-1), 16 (Neuron-Spectrum-2), 19 (Neuron-Spectrum-3), 21 (Neuron-Spectrum-4, Neuron-Spectrum-4/P) EEG channels, 1 (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3 and Neuron-Spectrum-4) or up to 4 polygraphic channels (Neuron-Spectrum-4/P: ECG, EOG), 1 breath channel and 2 direct current channels (Neuron-Spectrum-4/P).</p> <p>Neuron-Spectrum.NET includes the Evoked potentials averaging function and Quantitative electroencephalography (qEEG), including specific parameters such as Rhythmicity, FFT power ratio and amplitude metrics.</p> <p>The devices do not provide alarms, do not provide automated event marking and do not provide to the user any diagnostic conclusion about the patient's condition. They are intended for use in the patient care institutions, diagnostics centers, neurosurgical hospitals experimental laboratories and sleep laboratories. The patient group includes all ages and sexes.</p>	<p>The Blackrock NeuroMedCervello Rio-Potential Signal Acquisition Product Family contains the following configurations.</p> <p>Ambulatory: Up to 64 channels with one Cervello hardware device (Amplifier) using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG. The Cervello Ambulatory system does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.</p> <p>Basic: Up to 64 channels with one Cervello hardware device (Amplifier) and up to 128 channels by cascading 2 Cervello devices using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG. The Cervello Basic system does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.</p>

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM-1,2,3,4,4/P NEUROSOFT Ltd (Submitted Product)	LEGALLY MARKETED PREDICATE DEVICES OF Cervello™ Bio-Potential Signal Acquisition System Blackrock NeuroMedLLC
		<p>Elite: Up to 128 with one Neuroport Bio-Potential Recording Systems and up to 256 by cascading two Neuroport systems using the Central and/or Cervello software. The system supports recording., processing and display of bio-potential signals from user-supplied electrodes. Bio-potential signals include: Electrocorticography (ECoG), Electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrooculography (EOG) and Evoked Potential (EP). Intended users include Physicians, technicians, clinicians or other medical professionals that are trained in bio-potential and/or EEG recording. The Cervello Elite System does not make judgement of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.</p>

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM-1,2,3,4,4/P NEUROSOFT Ltd (Submitted Product)	LEGALLY MARKETED PREDICATE DEVICES OF Cervello™ Bio-Potential Signal Acquisition System Blackrock NeuroMedLLC
Intended Use	<p>The digital systems Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P with Neuron-Spectrum.NET software are intended for use as digital neurophysiological systems intended for recording, processing and display biopotential signals such as Electroencephalography (EEG) and long-latency Evoked Potential (EP). Polysomnography (PSG) derives from Electroencephalography (EEG) by the means of a dedicated software module and dedicated electrodes. The devices are portable and can register up to 8 (Neuron-Spectrum-1), 16 (Neuron-Spectrum-2), 19 (Neuron-Spectrum-3), 21 (Neuron-Spectrum-4, Neuron-Spectrum-4/P) EEG channels, 1 (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3 and Neuron-Spectrum-4) or up to 4 polygraphic channels (Neuron-Spectrum-4/P: ECG, EOG), 1 breath channel and 2 direct current channels (Neuron-Spectrum-4/P). Neuron-Spectrum.NET includes the Evoked potentials averaging function and Quantitative electroencephalography (qEEG) , including specific parameters such as Rhythmicity, FFT power ratio and amplitude metrics.</p> <p>The devices do not provide alarms, do not provide automated event marking and do not provide to the user any diagnostic conclusion about the patient's condition. They are intended for use in the patient care institutions, diagnostics centers, neurosurgical hospitals experimental laboratories and sleep laboratoriesThe patient group includes all ages and sexes.</p>	<p>Ambulatory- Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array and user-specified electrode locations.</p> <p>Basic- Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array and user-specified electrode locations.</p> <p>Elite- Acquire, amplify, record, display, digitize, retrieval, store and display bio-potential signals</p>
Clinical applications	Bio-potential signal amplification, recording, display, digitization, retrieval.	Bio-potential signal amplification, recording, display, digitization, retrieval.
Intended Users	Physicians and clinicians or other medical professionals that are trained in bio-potential recording	Physicians, technicians, clinicians or other medical professionals that are trained in bio-potential recording
Intended Use Environment	Care institutions, diagnostic centres, neurosurgical hospitals experimental laboratories and sleep laboratories of research institutions	Clinics, hospitals, operating rooms, epilepsy evaluation unit environments, sleep laboratories

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM-1,2,3,4,4/P NEUROSOFT Ltd (Submitted Product)	LEGALLY MARKETED PREDICATE DEVICES OF Cervello™ Bio-Potential Signal Acquisition System Blackrock NeuroMedLLC
Target patient population	Adults and newborns	Adults and paediatrics
Use limitations	The device is not a monitoring system and no physiologic alarms are provided. The acquisition and display of biopotential signals is for the interpretation and use of the clinician. The devices do not make any judgment of normality or abnormality of the displayed signals.	The System is not a monitoring system. No physiologic alarms are provided. The acquisition and display of biopotential signals is for the interpretation and use of the clinician. The devices do not make any judgment of normality or abnormality of the displayed signals.
Bio-Potential Signals Recorded	Electroencephalography (EEG) Electrocardiography (ECG) Electrooculography (EOG) Evoked potential (EP), Video EEG, PSG Respiration	Electroencephalography (EEG) Electrocorticography (ECoG} Electrocardiography (ECG) Electromyography (EMG) Electrooculography (EOG) Evoked potential (EP) Video EEG, Respiration, Heart rate, SPO2
Number of Signal Recording Channels	up to 8 (Neuron-Spectrum-1), 16 (Neuron-Spectrum-2), 19 (Neuron-Spectrum-3), 21 (Neuron-Spectrum-4, Neuron-Spectrum-4/P) EEG channels, 1 breath channel (Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum-4/P) 2 direct current channels (Neuron-Spectrum-4/P).	Up to 128 with one device and up to 256 by cascading two NeuroPortBiopotential devices
AnalogInput Channels (per unit)	28	16
Sampling rate	100, 200, 500, 1000, 2000, 5000 Hz	256 Hz Up to 30,000 Hz

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM-1,2,3,4,4/P NEUROSOFT Ltd (Submitted Product)	LEGALLY MARKETED PREDICATE DEVICES OF Cervello™ Bio-Potential Signal Acquisition System Blackrock NeuroMedLLC
Power source	Supply voltage: <ul style="list-style-type: none">• electronic unit: 5V DC• desktop PC-based system: 220/230 V AC (50 Hz)• notebook PC-based system: 220/230 V AC (50 Hz) / int. battery	Five-channel external power supply with sequencing, 120VAC / 60Hz input or 220VAC / 50Hz input
Software	Neuron-Spectrum.NET Software	Cervello™ and Interface to NeuroExplorer, Spike2, MATLAB, C/C++, and other 3rd-party software
Videocamera	available	available
Alarms	No	no
Digital resolution	32/64 bits	16 bits
Input noise EEG (rms value)	Within 0.5-200 Hz not more than 2 µV (not more than 0.3 µV)	< 3 µV
Input impedance EEG	not less than 400 MΩ	1000 MΩ (amplifier input impedance)
High pass filter	0.05–10 Hz (step 0.01 Hz)	0.3 to 7.5 Hz (amplifier frequency response)
Low pass filter	5–200 Hz (step 0.1 Hz)	Not stated
Connection to patient	By means of EEG, ECG, EOG, PSG electrodes and sensors (respiratory sensors, snoring sensor, body position sensor, electrodes)	User supplied electrodes
Acquired and displayed events:		
EEG	Yes (Neuron-Spectrum-1,2,3,4,4/P)	Yes
ECG	Yes (Neuron-Spectrum-1,2,3,4,4/P)	Yes
EOG (eye movement)	Yes (Neuron-Spectrum-1,2,3,4,4/P)	Yes
Evoked potential (EP)	Yes (Neuron-Spectrum-1,2,3,4,4/P)	Yes
Body Position	Yes (Neuron-Spectrum-4/P)	Not stated
Chest movements	Yes (Neuron-Spectrum-4/P)	Not stated
CPAP pressure	Yes (Neuron-Spectrum-4/P)	Not stated
Air Flow	Yes (Neuron-Spectrum-1,2,3,4,4/P)	Yes
Nasal Flow Pressure	Yes (Neuron-Spectrum-4/P)	Not stated

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM-1,2,3,4,4/P NEUROSOFT Ltd (Submitted Product)	LEGALLY MARKETED PREDICATE DEVICES OF Cervello™ Bio-Potential Signal Acquisition System Blackrock NeuroMedLLC
Abdominal movements	Yes(Neuron-Spectrum-4/P)	Not stated
Snoring	Yes(Neuron-Spectrum-4/P)	Not stated
Oximeter	No	yes
Safety Standard Compliance	IEC 60601-1:1988+A1:1991+A2:1995 IEC 60601-1-1:2000 IEC 60601-2-26:2002 IEC 60601-1-2:2007 IEC 60601-1-6-2006 IEC 62304-2006	IEC 60601-1-1998 IEC 60601-1-2:2007 IEC 60601-2-26: 2002

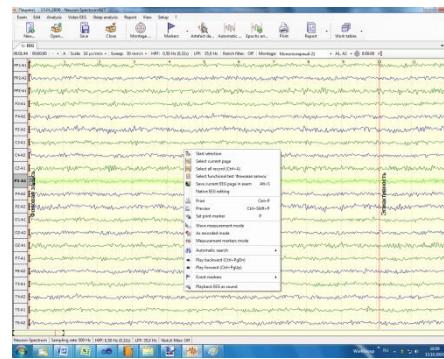
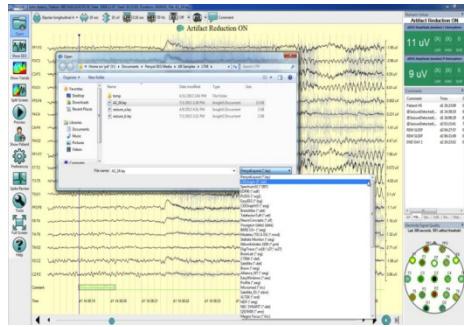
12.4 Table . Software Comparison with the Predicate Device Persyst 12 EEG Review and Analysis Software

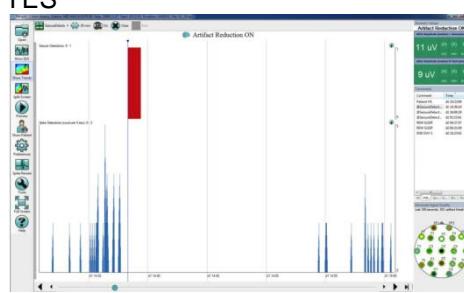
The functions of the Neuron-Spectrum.NET software are almost the same as the software of the predicate device Persyst12, that use similar software to collect, store and visualize signals. These functions are generic for all two devices.

ATTRIBUTE / CHARACTERISTICS	Neuron-Spectrum.NET (Submitted Product)	Software	NEUROSOFT	LEGALLY MARKETED PREDICATE DEVICES OF Persyst 12 EEG Review And Analysis Software Persyst Development Corp.
'K" numbers	K133995			K132306
Proprietary / Trade Name	Neuron-Spectrum.NET Software			Persyst 12 EEG Review And Analysis Software
CFR Section	882.1400			882.1400
Pro-code	OLT, OLV, GWQ			OMB, OLT,OMA
Classification name	Automatic Event Detection Software For Full-Montage Electroencephalograph			Automatic Event Detection Software For Full-Montage Electroencephalograph

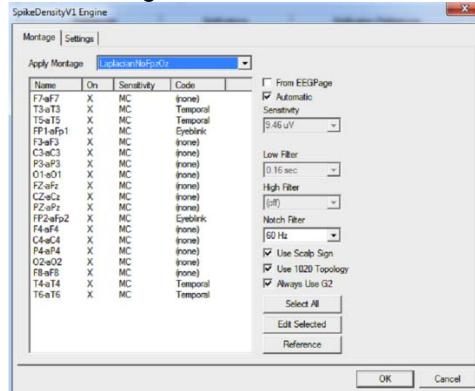
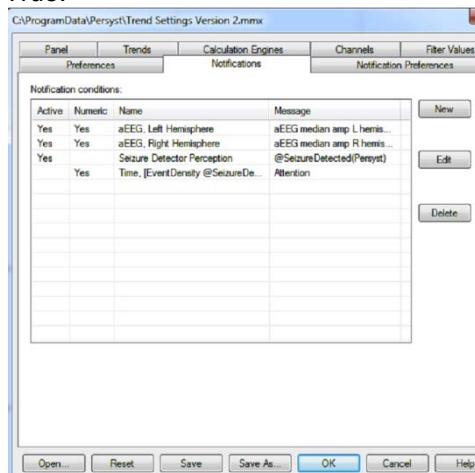
ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
'K" numbers	K133995	K132306	
Indications For Use	<p>The digital systems Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum-4/P with Neuron-Spectrum.NET software are intended for use as digital neurophysiological systems intended for recording, processing and display biopotential signals such as Electroencephalography (EEG) and long-latency Evoked Potential (EP). Polysomnography (PSG) derives from Electroencephalography (EEG) by the means of a dedicated software module and dedicated electrodes.</p> <p>The devices are portable and can register up to 8 (Neuron-Spectrum-1), 16 (Neuron-Spectrum-2), 19 (Neuron-Spectrum-3), 21 (Neuron-Spectrum-4, Neuron-Spectrum-4/P) EEG channels, 1 (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3 and Neuron-Spectrum-4) or up to 4 polygraphic channels (Neuron-Spectrum-4/P: ECG, EOG), 1 breath channel and 2 direct current channels (Neuron-Spectrum-4/P).</p> <p>Neuron-Spectrum.NET includes the Evoked potentials averaging function and Quantitative electroencephalography (qEEG) , including specific parameters such as Rhythmicity, FFT power ratio and amplitude metrics.</p> <p>The devices do not provide alarms, do not provide automated event marking and do not provide to the user any diagnostic conclusion about the patient's condition. They are intended for use in the patient care institutions, diagnostics centers,</p>	<p>1- Persyst 12 EEG Review and Analysis Software is intended for the review, monitoring and analysis of EEG recordings made by electroencephalogram (EEG) devices using scalp electrodes and to aid neurologists in the assessment of EEG. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.</p> <p>2- The Seizure Detection component of Persyst 12 is intended to mark previously acquired sections of adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic seizures, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with a full scalp montage according to the standard 10/20 system.</p> <p>3- The Spike Detection component of Persyst 12 is intended to mark previously acquired sections of the patient's EEG recordings that may correspond to spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. The Spike Detection component is intended to be used in patients at least one month old. Persyst 12 Spike Detection performance has not been assessed for intracranial recordings.</p> <p>4- Persyst 12 includes the calculation and display of a set of quantitative measures intended to monitor and</p>	

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
	neurosurgical hospitals experimental laboratories and sleep laboratories. The patient group includes all ages and sexes.	<p>analyze the EEG waveform. These include FFT, Rhythmicity, Peak Envelope, Artifact Intensity, Amplitude, Relative Symmetry and Suppression Ratio.</p> <p>Automatic event marking is not applicable to the quantitative measures. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG waveforms.</p> <p>5- The aEEG functionality included in Persyst 12 is intended to monitor the state of the brain. The automated event marking function of Persyst 12 is not applicable to aEEG.</p> <p>6- Persyst 12 provides notifications for seizure detection, quantitative EEG and aEEG that can be used when processing a record during acquisition. These include an on screen display and the optional sending of an e-mail message. Delays of up to several minutes can occur between the beginning of a seizure and when the Persyst 12 notifications will be shown to a user. Persyst 12 notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.</p> <p>7- Persyst AR (Artifact Reduction) is intended to reduce EMG, eye movement, and electrode artifacts in a standard 10-20 EEG recording. AR does not remove the entire artifact signal, and is not effective for other types of artifacts. AR may modify portions of waveforms representing cerebral activity. Waveforms must still</p>	

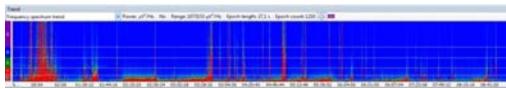
ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness	
		<p>be read by a qualified medical practitioner trained in recognizing artifact, and any interpretation or diagnosis must be made with reference to the original waveforms.</p> <p>8- This device does not provide any diagnostic conclusion about the patient's condition to the user.</p>		
Functions				
1-EEG Review	Waveform	 	Both windows show EEG waveforms coming from all the electrodes positioned on a head. The difference between the panels is in the order and the icons that enable the visualization and analysis of any single channel. In both cases each derivation can be analyzed in amplitude and frequency. In both cases the montage can be selected and different filter applied. So there isn't any difference that adversely affect the safety and effectiveness	
2-EEG & Archiving	Video	<p>YES</p> <p>Neuron-Spectrum-Video.NET program adds the possibility of video and audio recording synchronously with EEG being recorded. After the exam performing, you can edit the recorded video and audio and save the most interesting fragments in the exam.</p>	<p>YES</p> <p>Archive Video: if this option is selected then accompanying video will be archived with the fragments of marked EEG with the event text.</p>	Both softwares perform the video recording together with the EEG recording. But Neuron-Spectrum.NET enables also the audio recording adding functionality with respect to Persyst12. The audio recording system is safe because the acquisition is performed with an audio acquisition

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
			<p>connected to the instrument through safe and secure connections.</p> <p>Thus, there isn't any difference that adversely affect the safety and effectiveness</p>
3- Off-Line Seizure Detection	NO	<p>YES</p> 	<p>In Neuron-Spectrum.NET automatic tool for seizure detection is not provided. Neuron-Spectrum.NET ensures only manual marking of epileptiform activity fragments. All the detected fragments of epileptiform activity are marked by the color on the traces, displayed in "Navigator", "Exam Inspector" and epileptiform activity analysis windows.</p> <p>In Persyst 12 the seizure detector runs as a part of Persyst trending. The Seizure Detection trend uses a line graph to show the output of the Persyst Seizure Detector. Its value is one when a seizure is detected and zero when no seizure is detected. There are no user-adjustable parameters. During the processing of the current record the software will simultaneously run seizure detection, spike detection, and trending. If the record processing was already</p>

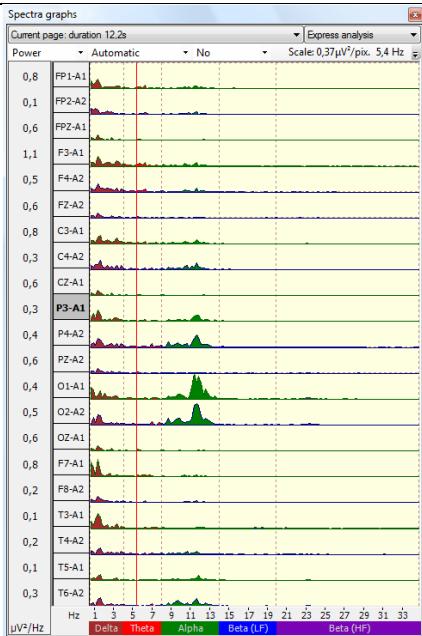
ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
			<p>started, you can continue it from the fragment it was left off. It will process new data as it arrives if the record is currently being acquired. Events can be reviewed in succession by using the Comment List. In this window, using the button SzDetect, you can see Persyst Seizure Detection events only.</p> <p>This function is present only in Persyst 12 and is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.</p>
4- Off-Line Spike Detection	NO	<p>YES</p> <p>The Persyst Spike Detector is run automatically when the EEG recording is processed. A Spike Density trend generates a graphical depiction of information shown in Spike text comments that were generated during Persyst Spike Detector's algorithmic analysis of EEG recording. An output value concerning spike detection frequency is plotted as a function of time.</p> <p>Spike detection is performed by the SpikeDensityV101 Calculation Engine, which can be viewed by selecting</p>	<p>This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.</p>

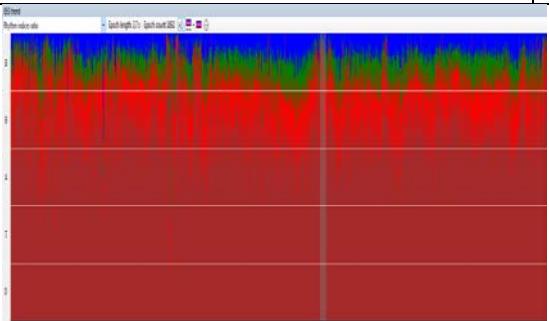
ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
		<p>Preferences TrendPreferences Calculation Engines.</p> 	
5- Notifications	NO	<p>YES</p> <p>Visual and email notifications can be set to identify events of interest. A Notification is triggered when a condition trend becomes True.</p> 	<p>This function is only in Persyst 12, it is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.</p>
6- Trend Type: Artifact Intensity	No	<p>YES</p> <p>The Artifact Intensity trend displays color-scaled indicators representing the</p>	<p>This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for</p>

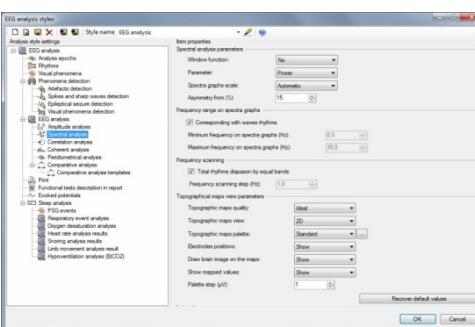
ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
		presence of three physiological non-cerebral signals (muscle, vertical saccadic eye movement/blink, and lateral saccadic eye movement) in the EEG as a function of time. The values graphed in this trend are outputs of intermediate steps in the Seizure Detection and Artifact Reduction algorithm, and are intended to be used in conjunction with the original EEG waveforms, and with other EEG trends, for analysis of the EEG.	diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
7-Trend Type: Electrode Signal Quality	NO	YES The Electrode Signal Quality trend displays horizontal bar indicators representing the presence of possible electrode artifact in the montage being used for EEG trend measures as a function of time. The values graphed in this trend are outputs of intermediate steps in the Artifact Reduction algorithm, and are intended to be used in conjunction with the original EEG waveforms, and with other EEG trends, for analysis of the EEG	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
8- Trend Type: Seizure detection	NO	YES The Seizure Detection trend uses a line graph to show the output of the Persyst Seizure Detector. Its value is one when a seizure is detected and zero when no seizure is detected. There are no user adjustable parameters.	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes.
9-Trend Type: Rhythmicity Spectrogram	YES The "Trend" window is intended to display the different trends of the record. Using the toolbar it is possible to select the trend type: the trend of the frequency spectrum, the trend of standard EEG	YES The Rhythmicity Spectrogram trend displays a density spectral array of frequency and power characteristics of the EEG as a function of time. Time is displayed on the x-axis, frequency on the y-axis, and a measure of EEG power on the z-axis	In both softwares there is a special trend to represent Frequency spectrum, which can show rhythmicity spectrogram during examination. Differences in the mapping do not affect the safety and

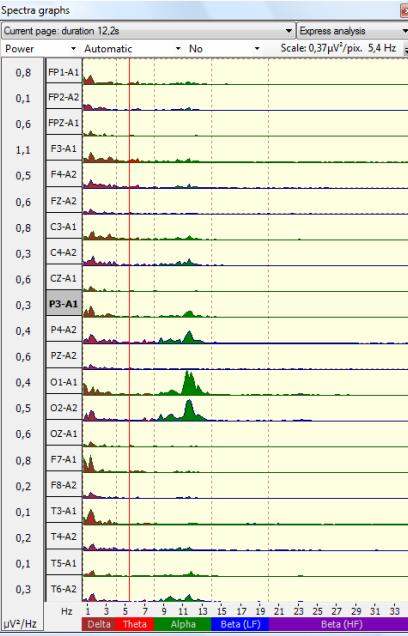
ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
	<p>rhythms indices, the trend of the average or maximum EEG amplitude, etc.</p> <p>It is also possible to select Frequency spectrum trend, which displays a density spectral array of frequency and power characteristics of the EEG as a function of time. Time is displayed on the x-axis, frequency on the y-axis, and a measure of EEG power on the z-axis as a color scale. User can set any colors.</p> <p>Density spectral array is calculated as fast Fourier transform for each time block of data by formula:</p> $X_k = \sum_{n=0}^{N-1} x_n e^{-i2\pi k \frac{n}{N}} \quad k = 0, \dots, N - 1.$  <p>The frequency spectrum trend.</p>	<p>as a color scale. The Rhythmicity Spectrogram provides a graphical depiction of the amplitude of primary rhythmic EEG components present in four frequency bands spanning 1-25 Hz. The Rhythmicity function is intended to be used in conjunction with the original EEG waveforms, and with other EEG trends, for analysis of the EEG.</p>	effectiveness.
10-Trend Type: FFT Spectrogram with Square-Root (SQRT) Scaling, Left and Right Hemisphere	NO	YES	<p>This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes.</p> <p>So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.</p>
11-Trend Type: EEG Asymmetry Index	NO	YES	<p>This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes.</p>

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
(EASI)			So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
12- Trend Type: Relative EEG Asymmetry Index (REASI)	NO	YES	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes.
13- Trend Type: Asymmetry, Relative Spectrogram (REASI Spectrogram)	NO	YES	So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
14- Trend Types: FFT Power Ratio	YES <p>The spectra IEEG analysis performed with the use of the fast Fourier transform(FFT) allows to transfer there recorded signal from the time scale to the frequency one.The use of the frequency notation of the signal is the integral part of the modern mathematical EEG analysis.</p>	YES <p>The FFT Power Ratio trend displays a line graph of a ratio of power in two user specified frequency bands of the EEG, derived from a fast Fourier transform analysis, as a function of time. Time is displayed on the x-axis and the power ratio result on the y-axis.</p>	In Neuron-Spectrum.NET software there is a special Frequency spectrum trend, which can show rhythmicity spectrogram during examination. Also there is a trend Rhythm indexes ratio, which can show FFT power ratio by rhythms bands, defined by user. Both softwares perform this function.

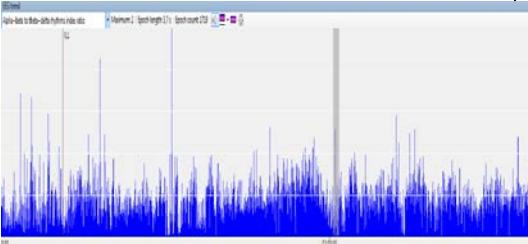
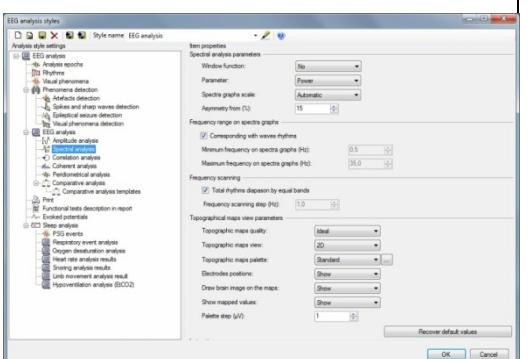
ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
	 <p>In "Trend" window there is a Rhythm indexes ratio trend, which displays a line graph of a ratio of power in several user specified frequency bands of the EEG, derived from a fast Fourier transform analysis, as a function of time. Time is displayed on the x-axis and the power ratio result on the y-axis. User-specified frequency bands are marked by color:</p>		

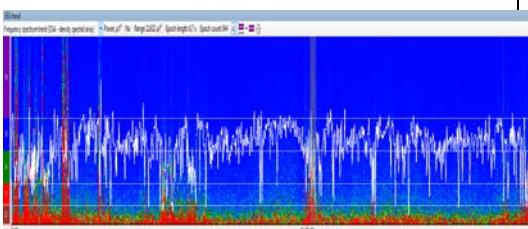
ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
	 Rhythm indexes ratio trend		
15- Trend Types: aEEG Left + Right	NO	YES The aEEG trend displays the amplitude characteristics of a filtered, rectified representation of the EEG signal as a function of time. Time is displayed on the x-axis and the aEEG amplitude is measured on the y-axis. The aEEG trend provides a simplified depiction of amplitude characteristics of the EEG signal, and is intended to be used in conjunction with other EEG trends, and with the original EEG waveforms, for analysis of the EEG.	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
16- Trend Type: Suppression Ratio	NO	YES	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
17- Trend Type: Spike Density	NO	YES A Spike Density trend generates a graphical depiction of information contained in Spike text comments that were generated during Persyst Spike Detector's	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
		algorithmic analysis of an EEG recording. An output value concerning spike detection frequency is plotted as a function of time	Neuron-Spectrum.NET does not affect the safety and effectiveness.
18- Spike Detections (count per 5 sec)	NO	YES Spike Detections (count per 5 sec): A Spike Density trend generates a graphical depiction of information shown in Spike text comments that were generated during Persyst Spike Detector's algorithmic analysis of an EEG recording. An output value concerning spike detection frequency is plotted as a function of time.	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence in Neuron-Spectrum.NET does not affect the safety and effectiveness.
19- Trend Type: Peak Envelope 2-20 Hz Left + Right	NO	YES The Peak Envelope trend displays a time-smoothed representation of a band-pass-filtered EEG's maximal amplitude envelope as a function of time. Time is displayed on the x-axis and the Peak Envelope amplitude is measured on the y-axis.	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
20- FFT Spectrogram	YES  The "Spectral analysis" page contains the parameters of the spectral analysis. It is	YES The FFT Spectrogram trend displays a density spectral array of the frequency and power characteristics of the EEG, derived from a fast Fourier transform analysis, as a function of time. Time is displayed on the x-axis, frequency on the y-axis, and a measure of EEG power on the z-axis as a color scale.	Both softwares perform this function, however the visualization is different.

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
	<p>possible to set the window function (to smooth the edge effects), analysis parameter (the amplitude or the power), the scale of the spectrum graphs. Also for the spectrum graphs, it is possible to indicate the frequency range which is visible on them.</p> <p>The Spectra graph analysis window allows to review FFT spectrogram by EEG derivations.</p>  <p>"Spectrumgraphs"window In "Trend" window there is a Frequency spectrum trend, which displays a density</p>		

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
	<p>spectral array of the frequency and power characteristics of the EEG, derived from a fast Fourier transform analysis, as a function of time. Time is displayed on the x-axis, frequency on the y-axis, and a measure of EEGpower on the z-axis as a color scale.</p>  <p>Frequency spectrum trend</p>		
21- FFT Power	NO	<p>YES</p> <p>The FFT Power trend displays a line graph of power in a user-specified frequency band of the EEG, derived from a fast Fourier transform analysis, as a function of time. Time is displayed on the x-axis and a measure of EEG power on the y-axis.</p>	<p>In Neuron-Spectrum.NET software only Total power spectrum trend is available, which displays a line graph of power in all frequency band of the EEG, derived from a fast Fourier transform analysis, as a function of time. Time is displayed on the x-axis and a measure of EEG power on the y-axis.</p> <p>So, in Neuron-Spectrum.NET software user can't specify spectrum bands to calculate power.</p>
22- FFT Power Ratio	<p>YES</p> <p>In "Trend" window several trends are available, which can show FFT power ratio: Alpha and delta index ratio, Alpha and theta index ratio, Alpha and beta index ratio, Alpha+beta to theta+delta index ratio. User can define frequency bands for delta, theta, alpha and beta rhythms.</p> <p>This trends display a line graph of a ratio of power in two user-specified</p>	<p>YES</p> <p>The FFT Power Ratio trend displays a line graph of a ratio of power in two user-specified frequency bands of the EEG, derived from a fast Fourier transform analysis, as a function of time. Time is displayed on the x-axis and the power ratio result on the y-axis.</p>	<p>The both softwares perform this function, however the visualization is different.</p>

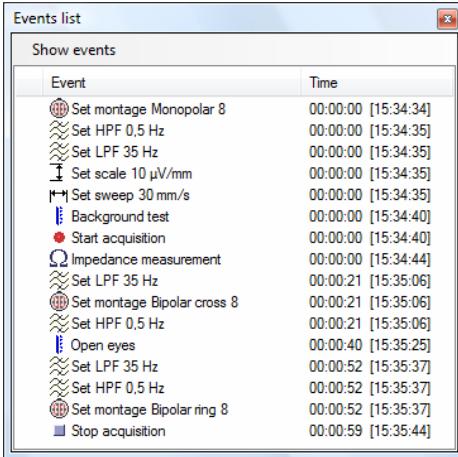
ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
	<p>frequency bands of the EEG, derived from a fast Fourier transform analysis, as a function of time. Time is displayed on the x-axis and the power ratio result on the y-axis.</p>  <p>Alpha+beta to theta+delta index ratio trend</p>		
23- FFT Edge	<p>YES</p>  <p>The “Spectral analysis” page contains the parameters of the spectral analysis. It is possible to set the window function (to smooth the edge effects), analysis parameter (the amplitude or the</p> <p>YES</p> <p>The FFT Spectral Edge trend displays a line graph, as a function of time, of the frequency below which a designated percentage of a user-specified EEG frequency band's total power is present. Time is displayed on the x-axis and the spectral edge frequency (Hz) on the y-axis. For example, for the frequency band 0-20 Hz and Edge percentage setting of 95, a resulting Spectral Edge value of 14 Hz means that 95% of the EEG's power in the 0-20 Hz range occurs below a frequency of 14 Hz.</p> <p>In Neuron-Spectrum.NET software a user can setup Frequency spectrum trend to show FFT edge, using context menu of the Trends window. Also user can set spectral edge calculation percent. Both softwares perform this function, even if the visualization is different.</p>		

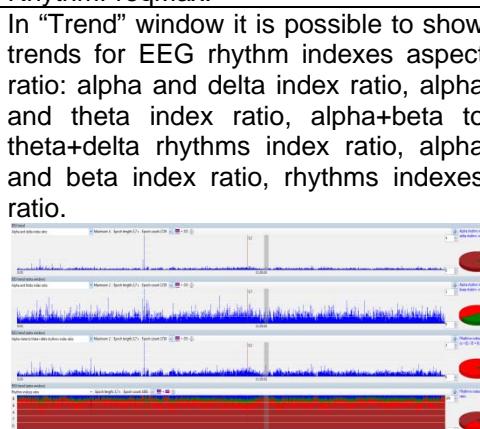
ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
	<p>power), the scale of the spectrum graphs. Also for the spectrum graphs, it is possible to indicate the frequency range which is visible on them. In "Trend" window on "Density Spectral Array" trend it is possible to show FFT Edge, which displays percentage of a user-specified EEG frequency band's total power.</p>  <p>Frequency spectrum trend with FFT Edge</p>		
24- Trend Type: Amplitude Trend	<p>YES</p> <p>The "Trend" window is intended to display the different trends of the record. At the calculation of EEG amplitude trends, the current EEG amplitude is represented in the top part of the current position bar. The boundary values for the trend are given in the right part of the window. The boundary values are calculated automatically but you can change them. In the top part of the window (on the toolbar) the maximum amplitude, the length of the analysis epoch at the trend</p>	<p>YES</p> <p>The Amplitude trend displays amplitude, signal slope, zero-crossing frequency, or statistical information concerning amplitude, of the EEG signal as a function of time. Time is displayed on the x-axis and the amplitude is shown on the y-axis. The Amplitude trend is intended to be used in conjunction with other EEG trends, and with the original EEG waveforms, for analysis of the EEG.</p>	<p>Neuron-Spectrum.NET software contains EEG average amplitude and EEG maximum amplitude trend, which can show EEG amplitudes during examination by EEG derivations. Both softwares perform this function, even if the visualization is different.</p>

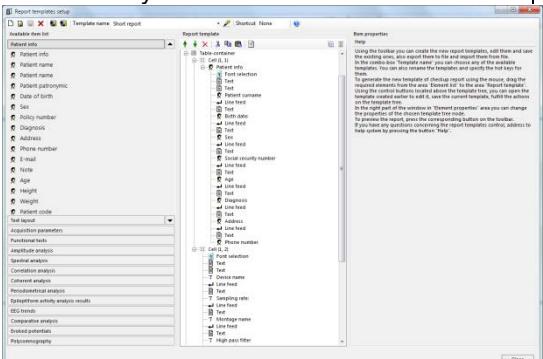
ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
	calculation and the epochs number are displayed.  The trend of average EEG amplitude		
25- Trend Type: Artifact Intensity	No	YES The Artifact Intensity trend displays color-scaled indicators showing the presence of three physiological non-cerebral signals (muscle, vertical saccadic eye movement/blink, and lateral saccadic eye movement) in the EEG as a function of time. The values graphed in this trend are outputs of intermediate steps in the Seizure Detection and Artifact Reduction algorithm, and are intended to be used in conjunction with the original EEG waveforms, and with other EEG trends, for analysis of the EEG.	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
26- Trend Type: Operation	NO	YES	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
27- Trend Type: Combination	NO	YES	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
28- Trend Type: Multi-Epoch	NO	YES	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
			diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
29- Trend Type: VsBkgnd	NO	YES	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
30- Trend Type: VsControl	NO	YES	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
31- Trend Type: Weighted Sum	NO	YES	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
32- Trend Types: Condition Threshold	NO	YES	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
33- Trend Types: Condition Boolean	NO	YES	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
34- Trend Types: Functional Algebra	NO	YES	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
35- Trend Types: Functional Constant	NO	YES	This function presented only in Persyst 12 is not fundamental to perform the analysis of EEG for diagnostic purposes. So the absence of this function in Neuron-Spectrum.NET does not affect the safety and effectiveness.
36- Trend Type: Event Density	<p>YES</p> <p>During EEG recording, a lot of events is recorded. To display these events and navigate over them, the "Event list" can be used. The events are divided into several groups:</p> <ul style="list-style-type: none"> • Service events – the events connected with the change of acquisition parameters (change of sweep speed, scale, montage, filters, etc.). The service events, as a rule, are not of interest to a user and are hidden by default. • User events – the event markers specified by a user. • Functional tests – the events of the beginning of the functional tests recording. • Stimulation events – the events connected with the stimulation during 	<p>YES</p> <p>An Event Density trend generates a graphical depiction of information shown in user-designated comments from the comments or comment file that accompanies an EEG recording. Either the presence or presence and duration of a user-specified comment can be graphed against time, or the presence of a specified comment and numeric data associated with that comment can be graphed against time.</p>	<p>Event list window in Neuron-Spectrum.NET allows to review all events marked during examination or filtered list of events. Both softwares perform this function, even if the visualization is different.</p>

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness																																		
	<p>an exam (the beginning of the stimulation, the end of the stimulation, the change of stimulation frequency, etc.).</p> <p>To filter the list of events in the window, it is possible to use "Show events" menu command.</p>  <table border="1"> <thead> <tr> <th>Event</th> <th>Time</th> </tr> </thead> <tbody> <tr><td>Set montage Monopolar 8</td><td>00:00:00 [15:34:34]</td></tr> <tr><td>Set HPF 0,5 Hz</td><td>00:00:00 [15:34:35]</td></tr> <tr><td>Set LPF 35 Hz</td><td>00:00:00 [15:34:35]</td></tr> <tr><td>Set scale 10 µV/mm</td><td>00:00:00 [15:34:35]</td></tr> <tr><td>Set sweep 30 mm/s</td><td>00:00:00 [15:34:35]</td></tr> <tr><td>Background test</td><td>00:00:00 [15:34:40]</td></tr> <tr><td>Start acquisition</td><td>00:00:00 [15:34:40]</td></tr> <tr><td>Impedance measurement</td><td>00:00:00 [15:34:44]</td></tr> <tr><td>Set LPF 35 Hz</td><td>00:00:21 [15:35:06]</td></tr> <tr><td>Set montage Bipolar cross 8</td><td>00:00:21 [15:35:06]</td></tr> <tr><td>Set HPF 0,5 Hz</td><td>00:00:21 [15:35:06]</td></tr> <tr><td>Open eyes</td><td>00:00:40 [15:35:25]</td></tr> <tr><td>Set LPF 35 Hz</td><td>00:00:52 [15:35:37]</td></tr> <tr><td>Set HPF 0,5 Hz</td><td>00:00:52 [15:35:37]</td></tr> <tr><td>Set montage Bipolar ring 8</td><td>00:00:52 [15:35:37]</td></tr> <tr><td>Stop acquisition</td><td>00:00:59 [15:35:44]</td></tr> </tbody> </table> <p>The events list.</p> <p>The events list displays the event name and the time of its beginning. As for the service events, you can see the astronomical time. To navigate to any event in the list, it is enough to click it with the left mouse button</p>	Event	Time	Set montage Monopolar 8	00:00:00 [15:34:34]	Set HPF 0,5 Hz	00:00:00 [15:34:35]	Set LPF 35 Hz	00:00:00 [15:34:35]	Set scale 10 µV/mm	00:00:00 [15:34:35]	Set sweep 30 mm/s	00:00:00 [15:34:35]	Background test	00:00:00 [15:34:40]	Start acquisition	00:00:00 [15:34:40]	Impedance measurement	00:00:00 [15:34:44]	Set LPF 35 Hz	00:00:21 [15:35:06]	Set montage Bipolar cross 8	00:00:21 [15:35:06]	Set HPF 0,5 Hz	00:00:21 [15:35:06]	Open eyes	00:00:40 [15:35:25]	Set LPF 35 Hz	00:00:52 [15:35:37]	Set HPF 0,5 Hz	00:00:52 [15:35:37]	Set montage Bipolar ring 8	00:00:52 [15:35:37]	Stop acquisition	00:00:59 [15:35:44]		
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37- Trend Types: EEG rhythms indexes	In "Trend" window it is possible to show trends for each EEG rhythm index: delta, theta, alpha and beta.	NO	These trends only duplicate information, which can be shown on "Density Spectral Array" trend, but in another way.																																		

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
	 <p>This trends can help to understand frequency bands, which dominate in examination.</p> <p>Rhythm indexes are calculated by this formula:</p> $\frac{\sum_{f=RhythmFreqMin}^{RhythmFreqMax} FFTPower(f)}{\sum_{f=FreqMin}^{FreqMax} FFTPower(f)} * 100\%$ <p>where FreqMin and FreqMax – minimum and maximum frequencies of total EEG frequency band, RhythmFreqMin and RhythmFreqMax – minimum and maximum frequencies of selected rhythm band. User can define FreqMin, FreqMax, RhythmFreqMin and RhythmFreqMax.</p>		
38- Trend Types: EEG rhythm indexes aspect ratio	<p>In "Trend" window it is possible to show trends for EEG rhythm indexes aspect ratio: alpha and delta index ratio, alpha and theta index ratio, alpha+beta to theta+delta rhythms index ratio, alpha and beta index ratio, rhythms indexes ratio.</p> 	NO	These trends only duplicate information, which can be shown on "Density Spectral Array" trend, but in another way to view rhythms aspect ratio.

ATTRIBUTE / CHARACTERISTICS	NEURON-SPECTRUM.NET SOFTWARE NEUROSOFT (Submitted Product)	PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE PERSYST DEVELOPMENT CORP.	Why the differences do not adversely affect the safety and effectiveness
	<p>Rhythm indexes are calculated by this formula:</p> $\frac{\sum_{f=RhythmFreqMin}^{RhythmFreqMax} FFTPower(f)}{\sum_{f=FreqMin}^{FreqMax} FFTPower(f)} * 100\%$ <p>where FreqMin and FreqMax – minimum and maximum frequencies of total EEG frequency band, RhythmFreqMin and RhythmFreqMax minimum and maximum frequencies of selected rhythm band. User can define FreqMin, FreqMax, RhythmFreqMin and RhythmFreqMax.</p>		
39- Report generating system by templates	<p>"Neuron-Spectrum.NET" software contains examination report system for automatical report generation by templates. In report template user can select what informant about examination he/she wants to include to the report and report will be generated automatically.</p>  <p>Reports template editor window This function allows to create examination reports quickly and easy.</p>	NO	<p>This tool allows to create exam report by predefined templates that is very fast for each examination.</p>

12.5Table - Comparison of stimulators for NEURON-SPECTRUM-1,2,3,4,4/P, Focus EMG Device and Neurofax m EEG-9100

Characteristics	Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4, Neuron-Spectrum-4/P (this submission)	Predicate device Focus EMG Device Neurosoft Ltd. TeleEMG LLC. (K102610)	Predicate device Nihon Kohden Neurofax m EEG-9100 (K011204)
Intended Use	<p>The digital systems Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum-4/P with Neuron-Spectrum.NET software are intended for use as digital neurophysiological systems intended for recording, processing and display biopotential signals such as Electroencephalography (EEG) and long-latency Evoked Potential (EP). Polysomnography (PSG) derives from Electroencephalography (EEG) by the means of a dedicated software module and dedicated electrodes.</p> <p>The devices are portable and can register up to 8 (Neuron-Spectrum-1), 16 (Neuron-Spectrum-2), 19 (Neuron-Spectrum-3), 21 (Neuron-Spectrum-4, Neuron-Spectrum-4/P) EEG channels, 1 (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3 and Neuron-Spectrum-4) or up to 4 polygraphic channels (Neuron-Spectrum-4/P: ECG, EOG), 1 breath channel and 2 direct current channels (Neuron-Spectrum-4/P).</p> <p>Neuron-Spectrum.NET includes the Evoked potentials averaging function and Quantitative electroencephalography (qEEG), including specific parameters such as Rhythmicity, FFT power ratio and</p>	<p>The Focus is intended for use by a healthcare provider to perform nerve conductions and EMG studies as an aid in the evaluation of patients with diseases of muscle and nerves. The machine can also use electrical stimulus or sound stimulus for evoked potentials (EP) studies.</p>	<p>Neurofax m EEG-9100 is intended for use as Electroencephalograph. This Electroencephalograph realizes the conventional EEG's functions in a GUI (graphical user interface) environment. It is designed for both clinical and research use.</p>

Characteristics	Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4, Neuron-Spectrum-4/P (this submission)	Predicate device Focus EMG Device Neurosoft Ltd. TeleEMG LLC. (K102610)	Predicate device Nihon Kohden Neurofax m EEG-9100 (K011204)
	amplitude metrics.. The devices do not provide alarms, do not provide automated event marking and do not provide to the user any diagnostic conclusion about the patient's condition. They are intended for use in the patient care institutions, diagnostics centers, neurosurgical hospitals experimental laboratories and sleep laboratories. The patient group includes all ages and sexes.		
Safety	IEC 60601-1:1988+A1:1991+A2:1995 IEC 60601-1-2:2007 IEC 60601-2-26:2002 IEC 60601-1-1:2000 IEC 60601-1-6-2010 IEC 62304-2006	IEC 60601-1-1-2000 IEC 60601-1-2-2001 IEC 62471-2006	IEC 60601-1 (1988) IEC 60601-1 Amd 1 (1991) IEC 60601-1 Amd 2 (1995) IEC 60601-2-26 (1994) EN 60601-1-1 (1992-06) with AMI (1995-10) IEC 60601-1-2 (1993)
General system approach	Computer based equipment with dedicated hardware peripherals/components	Computer based equipment with dedicated hardware peripherals/components	notebook PC unit
Userinputdevice	Microsoft Windows mouse/keyboard driven graphic interface	Microsoft Windows mouse/keyboard driven graphic interface. Built-in keyboard	Microsoft Windows mouse
Useroutputdevice	No built-in output devices. Computer display and printer	Digital color display Commercial printers	Printer
Patient inputs	Up to 8 (Neuron-Spectrum-1), 16 (Neuron-Spectrum-2), 19 (Neuron-Spectrum-3), 21 (Neuron-Spectrum-4, Neuron-Spectrum-4/P) EEG channels, 1 (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3 and Neuron-Spectrum-4) or up to 4 polygraphic channels (Neuron-Spectrum-4/P: ECG, EOG), 1 breath channel and 2 direct current channels (Neuron-Spectrum-4/P)	2 channels preamplifiers, isolated	25 EEG, 4 Extra, 3 respiration inputs (flow, chest, abdomen), 6 Bipolar, 4 DC inputs

Characteristics	Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4, Neuron-Spectrum-4/P (this submission)	Predicate device Focus EMG Device Neurosoft Ltd. TeleEMG LLC. (K102610)	Predicate device Nihon Kohden Neurofax m EEG-9100 (K011204)
Trigger input (synchronization to external events)	Yes	Yes	Yes(1 to 5V)
Trigger output (synchronization for external devices)	Yes	Yes	Yes(3V or more)
Amplifier- Computer interface	USB	USB	USB
System Power Supply	Electronic unit: 5V DC System with Personal Computer: 100-120/200-240 V AC (50-60 Hz) System with Notebook: 100-120/200- 240 V AC (50-60 Hz)	Electronic unit: 5V DC System with Personal Computer: 100-120/200- 240 V AC (50-60 Hz) System with Notebook: 100- 120/200-240 V AC (50-60 Hz)	Power supply unit: 2A/250V (AC 100 to 127 V)(50/60Hz)
Size (H/W/D) mm	ElectronicUnit: 140x200x45 mm	ElectronicUnit: 90x270x50 mm	ElectronicUnit: 33.2x388x251 mm
Weight (complete system- kg)	Electronic Unit: not more than 0.9 kg System: not more than 12.5 kg	ElectronicUnit: 0.35 System: 3.5	PC unit: 2.33 kg Power supply unit: 3 kg Cart: 18.5 kg
Design - Acquisition			
Number of channels	Up to 8 (Neuron-Spectrum-1), 16 (Neuron-Spectrum-2), 19 (Neuron- Spectrum-3), 21 (Neuron-Spectrum-4, Neuron-Spectrum-4/P) EEG channels, 1 (Neuron-Spectrum-1, Neuron- Spectrum-2, Neuron-Spectrum-3 and Neuron-Spectrum-4) or up to 4 polygraphic channels (Neuron- Spectrum-4/P: ECG, EOG), 1 breath channel and 2 direct current channels (Neuron-Spectrum-4/P)	2 EMG	25 EEG, 4 Extra, 3 respiration inputs (flow, chest, abdomen), 6 Bipolar, 4 DC inputs
CMRR	Not less than 100 dB	>100 dB	105 dB or greater (at 60 Hz)
Noise	<=1 μ Vrms	< 0.6 μ Vrms.	Less than 1.5 μ Vp-p(0.53 to 60 Hz)
Input impedance	> 100 M Ω < 25pF	> 100 M Ω < 25pF	100M Ω

Characteristics	Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4, Neuron-Spectrum-4/P (this submission)	Predicate device Focus EMG Device Neurosoft Ltd. TeleEMG LLC. (K102610)	Predicate device Nihon Kohden Neurofax m EEG-9100 (K011204)
Lowpassfilter	(-12dB/octave) 5, 10, 15, 35, 75, 100, 150, 200, 250, 500 Hz	(-12dB/octave) 10, 20, 35, 50, 75, 100, 150, 200, 300, 500, 1000, 2000, 3000, 5000, 10000 Hz	0.08, 0.16, 0.27, 0.53, 1.6, 5.3, 53, 159 Hz (-6dB/oct)
High pass filter	(-6dB/octave) 0.05, 0.5, 0.7, 1.5, 2, 5, 10 Hz	(-6dB/octave) 0.05, 0.1, 0.2, 0.3, 0.5, 1, 2, 3, 5, 10, 20, 30, 50, 100, 200, 300, 500, 1000, 2000, 3000 Hz	15, 30, 35, 60, 70, 120(-12 dB/oct) 50 (RAPID), 300 Hz (-18 dB/oct)
Notchfilter	50/60 Hzselectable	50/60 Hzselectable	50 or 60 Hz
A/D conversion	16 Bit ADC	16 Bit ADC	16 Bit (97 nV/LSB)
Samplingrate	100 – 5000 Hz	200-80000 Hz	100, 200, 500, 1000 Hz
Analysistime	1s – 30s	2 ms - 5 min	
Signaldelay (pre/post)	0-10 s	0-10 s	The time must be set to 10 s or more.
Video Recording	Yes	No	No (digital video software)
Design – Stimulators			
Electrical Stimulator	No	Type: constant current N. output 1 Max output: 100 mA Pulse width: 0.1 - 5 ms Mode: single, train	No
Audio Stimulator	Output mode: click, tone Sound pressure: 0-126 dB SPL (TDH-39) Phase: condens., raref, alternate Signal frequency: 100-8000 Hz Click width: 100-5000 µs Stimulus presen:Left/right/double-sided Headset: TDH-39	Output mode: click, tone Sound pressure: 0-126 dB SPL (TDH-39) Phase: condens., raref, alternate Signal frequency: 100-8000 Hz Click width: 100-5000 µs Stimulus presen. Left, right, binaural Headset: TDH-39	No
Photic Stimulator	Click width: 0.1–3000 µs Stimulation frequency 0.1–100 Hz Stimulus present: Left/right/double-sided Photic stimulator (interface:connector for photo stimulator connection)	Stimulus duration: 2–1500 ms Stimulation frequency: 0.05–50Hz Stimulus present: Left / right / double-sided stimulation, LED goggles (interface: connector for photo stimulator connection)	Stimulation period: 1 to 99 seconds in 1 second steps Photic frequency 0.5 Hz, 1 to 33 Hz in 1 Hz steps, 50 and 60 Hz, Flash lamp assembly (interface: the PHOTIC LAMP connector on the rear of the photot control unit)
Basic EP Application Modules			
Somatosensory	No	Yes	No

Characteristics	Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4, Neuron-Spectrum-4/P (this submission)	Predicate device Focus EMG Device Neurosoft Ltd. TeleEMG LLC. (K102610)	Predicate device Nihon Kohden Neurofax m EEG-9100 (K011204)
EP			
Auditory EP	Yes	Yes	No
Visual EP (flash)	Yes	Yes	Yes
Visual EP (pattern)	Yes	Yes	No

Table 12.6Table - Comparison of outputs for NEURON-SPECTRUM-1,2,3,4,4/P and Alice 5 System

Sensor	Neuron-Spectrum-1 (this submission)	Neuron-Spectrum-2 (this submission)	Neuron-Spectrum-3 (this submission)	Neuron-Spectrum-4 (this submission)	Neuron-Spectrum-4/P (this submission)	Alice 5 System Respironics Inc. k040595
IFU	The digital systems Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3, Neuron-Spectrum-4 and Neuron-Spectrum- 4/P with Neuron-Spectrum.NET software are intended for use as digital neurophysiological systems intended for recording, processing and display biopotential signals such as Electroencephalography (EEG) and long-latency Evoked Potential (EP). Polysomnography (PSG) derives from Electroencephalography (EEG) by the means of a dedicated software module and dedicated electrodes. The devices are portable and can register up to 8 (Neuron-Spectrum-1), 16 (Neuron-Spectrum-2), 19 (Neuron-Spectrum-3), 21 (Neuron-Spectrum-4, Neuron-Spectrum-4/P) EEG channels, 1 (Neuron-Spectrum-1, Neuron-Spectrum-2, Neuron-Spectrum-3 and Neuron-Spectrum-4) or up to 4 polygraphic channels (Neuron-Spectrum-4/P: ECG, EOG), 1 breath channel and 2 direct current channels (Neuron-Spectrum-4/P). Neuron-Spectrum.NET includes the Evoked potentials averaging function and Quantitative electroencephalography (qEEG) , including specific parameters such as Rhythmicity, FFT power ratio and amplitude metrics. The devices do not provide alarms, do not provide automated event marking and do not provide to the user any diagnostic conclusion about the patient's condition. They are intended for use in the patient care institutions, diagnostics centers, neurosurgical hospitals experimental laboratories and sleep laboratoriesThe patient group includes all ages and sexes.					The Alice 5 System is a Polysomnography System that is intended to record, display and print information to clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adults or infant patients require documentation of various sleep or other physiological disorders. This device does not provide alarms and, Is not intended for use as an automated apnea monitor.
Product code	OLT, OLV, GWQ					OLZ, OLV
CFR section	882.1400					882.1400
Total Channel	8	16	19	21	21	55
EEG inputs	8	16	19	21	21	21
Input impedance	Not less than 400 MΩ					1.66 MΩ per Electrode 3.33 differential
Bandwidth	in range from 0.5 up to 60 Hz from -10 up to +5%					0.32 Hz to 106 Hz
Input signal range	1-12000µV					± 3.3 mV
Max sampling rate	5000 Hz					2000 Hz
Max storage rate	5000 Hz					200 Hz, limited 500 Hz
High pass filter	0.05-10 Hz					0.5 to 100 Hz
Low pass filter	5-200 Hz					0.5 to 100 Hz

Sensor	Neuron-Spectrum-1 (this submission)	Neuron-Spectrum-2 (this submission)	Neuron-Spectrum-3 (this submission)	Neuron-Spectrum-4 (this submission)	Neuron-Spectrum-4/P (this submission)	Alice 5 System Respironics Inc. k040595
Notch filter	not less than 40 dB					50 or 60 Hz
DC inputs	no	no	no	no	yes	yes
EOG	yes	yes	yes	yes	yes	yes
ECG channels	yes	yes	yes	yes	yes	yes
Pressure transducer	no	no	no	no	yes	yes
Effort (chest/abdominal)	no	no	no	no	yes	Piezo,RIP optional w/additional module
Body position	no	no	no	no	yes	yes
Snore	no	no	no	no	yes	yes
Flow (thermal)	yes	yes	yes	yes	yes	yes
Pulse oximetry	No	yes	yes	yes	yes	yes
Size	140x200x45 (mm)					10L x 4W x 2H (in)
Weight	not more than 0.9 kg					1.6 lb

Conclusion of the hardware equivalence

The Neuron-Spectrum-1,2,3,4,4/P with Spectrum.NET software acquire only a subset of the biopotentials collected by the predicate device Cervellobut this deficiency doesn't affect safety and effectiveness of the system, as demonstrated with the proper IEC tests.

Based on the information and supporting documentation provided in Section 12 Substantial Equivalence Discussion, Neuro-Spectrum-1, 2, 3,4, 4/P devices are substantially equivalent for the applicable features to the predicate devices FOCUS EMG and Neurofax m EEG-9100.

An auditory stimulator adapted for Neurosoft Ltd. is used. TDH-39 headphones are registered together with Focus device as K102610. These auditory stimulators are identical to those used in the subject device.

For photo stimulation a photic stimulator (LED stimulator) is used. LED stimulator can be attached to the Neuro-Spectrum-1, 2, 3 ,4, 4/P via photic stimulator connector located on a device panel (the same as Neurofax m EEG-9100)

A thorough comparison of outputs for NEURON-SPECTRUM-1,2,3,4,4/P and Alice 5 Polysomnography System is provided in Section 12 Substantial Equivalence Discussion.

A thorough comparison between the Neuron-Spectrum-1,2,3,4,4/P with Spectrum.NET software and Persyst 12 software is shown in a tabular form in the Section 12 Substantial Equivalence Discussion. All the characteristics that affect the safety and effectiveness of the system are compared and presented in a clear format.

All the third party sensors that are recommended to be used in the Neuron-Spectrum-1,2,3,4,4/P have prior 510(k) approval from FDA or they have biosafety tests (see Section 11.9). The specifications meet the requirements of the Draft FDA guidance for 510(k) content for Electroencephalograph Devices.

Discussion of minor differences in software features

The processing functions for both the subject device and predicate devices are well known and accepted as the conventional tools.

The Neuron-Spectrum.NET software resides on a PC like Persyst 12 and it has indications for use and characteristics that are a subset of the ones of Persyst 12. These functions are generic for all two devices.

As described Section 12 Substantial Equivalence Discussion the predicate substantially performs the same operations and the minor differences consist in:

- graphical appearance of the control icons;
- graphical appearance on displaying the results.

These minor differences do not raise any new hazard, they don't increase the risk of inappropriate image capture or the risk of an erroneous interpretation of the results by the operator or the risk of an erroneous processing.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of Neuron-Spectrum-1,2,3,4,4/P with Neuron-Spectrum.NET software and the predicate devices has been performed through the above comparative tables. The results of

this comparison demonstrate that the Neuron-Spectrum-1,2,3,4,4/P with Neuron-Spectrum.NET software is equivalent to the marketed predicate devices.

PERFORMANCE DATA

The performance data (IEC e ISO tests attached in Section 17), the Verification and Validation tests (Section 16.3), the Software Requirements Specifications (Section 16.4) indicate that the Neuron-Spectrum-1,2,3,4,4/P with Neuron-Spectrum.NET software device meets all specified requirements and that it is substantially equivalent to the predicate devices.

CONCLUSION STATEMENT

All the necessary electromagnetic compatibility and electrical safety tests were performed.

The results demonstrate that Neuron-Spectrum-1,2,3,4, 4/P with Neuron-Spectrum.NET is in compliance with both the standards IEC 60601-1-2 and IEC 60601-1 and is safe as the predicate device.

All the necessary performance tests in support of substantial equivalence determination were conducted and documented in section 18 “Performance testing”. The tests demonstrate that the Neuron-Spectrum-1,2,3,4,4/P with Neuron-Spectrum.NET is effective and performs as well as the predicate device.

So Neuron-Spectrum-1,2,3,4,4/P with Neuron-Spectrum.NET and CervelloTM can be considered substantial equivalent even if the design is different. In fact, even if the dimensions of the instruments are different, the electrodes have different shapes, the software has some differences in functionalities, they acquire, display and analyse biopotential signals such as Electroencephalography (EEG) , Evoked Potential (EP). AndPolysomnography (PSG).

The Neuron-Spectrum.NET software and Persyst 12 can be considered substantial equivalent even if the windows and the icons, i.e. the design, are different, as demonstrated by the comparison table 5.2. In fact the main core of the functions is the same.

The minor differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy.

Based on these results, we conclude that the Neuron-Spectrum-1,2,3,4,4/P with Neuron-Spectrum.NET are substantially equivalent to the existing legally marketed devices CervelloTM Bio-Potential Signal Acquisition System,FOCUS EMG , Neurofax m EEG-9100 and Alice 5 for the hardware configuration, and PERSYST 12 EEG REVIEW AND ANALYSIS SOFTWARE for the software configuration under Federal Food, Drug and Cosmetic Act.